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PHARMACY SECURITY BEST PRACTICES

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Pharmacy theft and robbery are serious problems fueled by the growing abuse of prescription drugs and their high street value. In discussing pharmacy security with interested parties representing the pharmacy community, the Division of Consumer Affairs has identified certain areas of concern. The intent of this document is to highlight these areas of concern and present potential solutions that pharmacists may consider employing to address those concerns.

The best practices outlined below are recommendations to achieve a safe operating environment for pharmacy employees and customers and lower the potential for adverse events. While implementation of some or all of the recommendations may be impossible for some pharmacies, all pharmacies are encouraged to implement as many of the best practices as they can manage.

Physical Security Controls of Controlled Dangerous Substances

1. Where practical Schedule II (C-II) and Schedule III (C-III) medications in solid dosage form, and other dosage forms (e.g. liquid) as space permits, should be stored in a safe or substantially constructed steel cabinet that is locked at all times (excluding filled C-II/C-III prescriptions located in the secured Will-call bins, see paragraph 3 in this section). All C-II and C-III medications that are required to be refrigerated should be kept in a locked refrigerator. Only licensed pharmacists should be permitted access to the safe/steel cabinet and locked refrigerator, and at no time should anyone else access the safe or locked refrigerator. All other CDS may continue to be dispersed throughout the non-controlled inventory.
2. The safe/steel cabinet should comply with the state and federal requirements for storage of small quantities of CDS by non-practitioners found at N.J.A.C. 13:45H-2.2(a)(1) and 21 C.F.R. 1301.72.
3. Will-call bins for C-II and C-III medications should be located in the secured prescription filling area of the pharmacy department (not on shelves by the cashier) and within unobstructed view of the pharmacist during the hours the pharmacy is open. Where practical, the bin should be constructed so that it can be securely locked at night and at all times when the pharmacy is closed.
4. N.J.A.C. 13:39-4.15(b)(3) requires that there be a secure area for receiving packages known to contain CDS, PLD and devices. No deliveries for prescription drugs shall be accepted during the hours the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided.

It is recommended that pharmacies receive deliveries of CDS/PLD only during posted store hours, and only when a pharmacist is present to accept and sign for the delivery.

It is recommended that upon receipt of CDS/PLD the pharmacist, or, if delegated by the pharmacist, a registered pharmacy technician, open and inspect the contents of the containers to ensure that the totes contain the correct CDS in the correct amounts as soon as practical after receiving delivery. Any discrepancy between the receipt/invoice and actual contents must be immediately reported per regulation. N.J.A.C. 13:39-4.15.

General Security for Pharmacy

1. Pharmacies must comply with regulatory requirements for a monitored security system which transmits an audible, visual or electronic signal warning of intrusion. The security system is required to be equipped with a back-up mechanism to ensure notification or continued operation if the security system is tampered with or disabled. The central station monitoring agreement should be paid for and current. N.J.A.C. 13:39-4.15(b)1

Pharmacies should consider a security system with a cellular backup mechanism to ensure notification or continued operation of the system in the event of power failure or the system is disabled.

2. Consider installing a silent panic alarm.
3. Do not allow unescorted, non-essential personnel in the prescription filling area or pharmacy department (plumbers, building inspectors, accountants, etc.). The RPIC should use due diligence in ensuring the security of the pharmacy as per N.J.A.C. 13:39-4.15
4. Pharmacies should consider utilizing video surveillance technology including quality security cameras placed to capture activity anywhere CDS is stored, counted, held, dispensed or returned to stock, and exits from the pharmacy or the "front end" of a retail store. At minimum, the tapes should be retained three months to help ID potential theft identified during random CDS manual counts. Pharmacies should consider updating to digital recording systems to enhance pharmacy security and reduce storage concerns.
5. Routine pharmacy security features include: alarmed doors/windows with central station monitoring, physical barriers (steel window/door curtains), sensors, sufficient lighting levels inside and outside the pharmacy, installation of height markers at exit doors.
6. Train staff for prevention and response to robbery.
7. Advertise security to the public and employees.
8. Unwanted or outdated CDS should be properly disposed of or returned per Federal and State regulations.

Frequency of CDS inventory and manual count of pills

1. A Pharmacist should consider maintaining a perpetual inventory for C-II and C-III medications and other items identified to have high street value, e.g. Alprazolam, diazepam, and possibly erectile dysfunction drugs, tramadol etc. The inventory should include:
 - Date, drug name, quantity received and invoice number or DEA Form 222 (or Electronic 222) for all medications received.
 - Date, drug name, quantity and prescription number for each prescription filled and dispensed.

- Date, drug name, quantity and prescription number for all medication that is filled but not dispensed and is returned to stock
 - Date, drug name, and quantity for all medication sent to a reverse distributor or destroyed as waste.
2. A pharmacist should conduct a random manual reconciliation once each month to include at least 5 drugs that are top 10% risk for diversion and 3 that are lower risk for diversion. The Pharmacist should manually sign and date the inventory and reconciliation paperwork each time he/she conducts a manual reconciliation. If the inventory and/or manual reconciliation paperwork is kept electronically, the pharmacist should print it out and manually sign it.

When a pharmacy employs more than one pharmacist, the same pharmacist should not conduct the monthly reconciliation count any two consecutive months.

3. Inventory and manual reconciliation results should be maintained for two years.
4. *Each* supplier's invoice for Schedule II CDS medications should be stapled to the corresponding DEA -222 Form (or CSOS print-out), on which the pharmacist has recorded the required information for each item received, and should be maintained in a separate file.
5. Inventory for all CDS (Schedule C-II through C-V) should be done once a year on the same day and month that your biennial inventory would usually be completed.

Ordering CDS and verification of shipment upon delivery

1. Only the pharmacist should have the authority to order C-II and C-III CDS.
2. As soon as possible after delivery of the CDS, a pharmacist or pharmacy technician may check-in the order. A pharmacist, other than the individual who did the initial check-in should verify the completeness and accuracy of each order and sign off on each receipt/invoice before placing the CDS into inventory, as described above. Only the pharmacist may physically place the C-II's and C-III's into the safe/steel cabinet.
3. The same person should not have responsibility for ordering and receiving CDS.

Interface with Prescribers

1. A pharmacist who suspects that a practitioner may be indiscriminately prescribing CDS should contact the practitioner to attempt to ascertain whether the prescription is being issued for a legitimate medical purpose. A pharmacist should report practitioners about whom they have substantiated concern to the appropriate professional licensing Board and the Prescription Drug Monitoring Program. N.J.S.A. 45:1-37.
2. A pharmacist who suspects a prescription may be forged or altered¹ should verify the prescriber's phone number to ensure that the number printed on the prescription blank is correct and call to confirm the prescription, verify suspicious oral prescriptions, ask for appropriate practitioner information such as DEA #, utilize caller ID to note telephone number of incoming call, verify ID of person picking up the prescription. A pharmacist

¹Some Characteristics of Forged Prescriptions: Prescriber is not from your local area • Patient is unfamiliar to you or is from out of town • Patient exhibits suspicious behavior • Patient is picking up prescription for someone else • Prescription is presented or phoned in near closing time • Prescription is phoned in by practitioner covering after hours or on the weekend • Prescription appears too perfect, or in the alternative, contains errors in spelling or prescribing symbols • Prescription appears to be copied or scanned, is not of proper size or does not appear to have been torn from an official prescription pad.

could also request a faxed confirmation from the practitioner's office, to confirm a telephone prescription.

3. Exercise caution with internet related transactions, especially fee for filling opportunities and deals that seem too good to be true.

Interface with Customers

1. Require individuals picking up CDS prescriptions to show photo identification at time of purchase if the pharmacist is not familiar with the patient. Photocopies of the identification should be stapled to the original prescription or scanned to the computer profile.
2. Written prescription blanks should not be stored in a way that would allow customer access. That is, kept where customers can reach them or see confidential patient information (to steal, wash, alter, etc.)
3. All pharmacists should register with Division's Prescription Monitoring Program, and should regularly access the PMP when filling prescriptions to monitor for instances of doctor-shopping or abuse. Pharmacies may also consider including drug abuse and treatment information on the drug monograph that is provided to each patient.
4. The pharmacist has the right to refuse to fill a prescription if, in his or her professional judgment, the prescription is outside the scope of the practice of the practitioner; or if the pharmacist has sufficient reason to question the validity of the prescription; or to protect the health and welfare of the patient. N.J.A.C. 13:39-7.12

Self Assessment

Registered Pharmacists in Charge should conduct self-assessments annually and whenever there is a change in RPIC, to ensure that federal and state requirements governing the practice of pharmacy are met. The self-assessment procedure evaluates a variety of concerns to include: pharmacy security measures in place, medication inventory review (expired, overfilled, misbranded, substituted, pilfered), prescription dispensing analysis, required equipment and documentation. The Board of Pharmacy is in the process of creating a self-assessment tool that would be New Jersey specific and available in the future.

REPORTING CDS RELATED THEFT/LOSS

Any theft/loss of CDS and PLD must be reported:

1. Contact local police department and report the theft/loss.
2. Submit a Report of Theft or Loss of Controlled Substances form (DDC-52) to the NJ Department of Law and Public Safety, Drug Control Unit.
3. Electronically submit a Report of Theft or Loss of Controlled Substances form (DEA-Form 106) to the Drug Enforcement Administration, Office of Diversion Control. The website is www.dea.gov/diversion. A paper version of DEA Form 106 can be obtained by writing DEA Headquarters, Attn: Regulatory Section/ODG, 8701 Morrisette Drive, Springfield, VA 22152.
4. Report the theft/loss to Anthony Rubinaccio, Executive Director, New Jersey Board of Pharmacy by submitting a copy of the DEA-Form 106.

Upon receiving notification that specific NJPB's have been reported lost or stolen by a practitioner and if presented, prior to dispensing:

1. Verify the prescription's authenticity with the prescriber.
2. Contact your local police department.
3. Submit a NJPB Incident Report to the NJPB Unit of the Division of Consumer Affairs.

To report a suspected indiscriminate/overprescribing practitioner, or an impaired practitioner, contact the practitioner's respective licensing Board by telephone. An online complaint form can also be filed (see the New Jersey Division of Consumer Affairs website at: <http://www.nj.gov/oag/ca/boards.htm>)

Disposal of unwanted or outdated CDS is accomplished by first completing a DEA Form 41 and submitting same to the Drug Enforcement Administration (DEA)(1-888-346-1071). The pharmacy would next contact the NJ Drug Control Unit, complete a DDC Form 51, submit same and await further instructions.

STATE OF NEW JERSEY
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NJPB Unit

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Drug Control Unit

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New Jersey Prescription Monitoring Program

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Enforcement Bureau

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New Jersey State Board of Medical Examiners

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